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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,982	05/02/2006	Makoto Koizumi	06189/HG	2978
1933 7590 11/05/2009 FRISHAUF, HOLTZ, GOODMAN & CHICK, PC 220 Fifth Avenue 16TH Floor NEW YORK, NY 10001-7708				
EXAMINER				
STAPLES, MARK				
ART UNIT		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/577,982

**Applicant(s)**

KOIZUMI, MAKOTO

**Examiner**

MARK STAPLES

**Art Unit**

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 8-17 and 19-45 is/are pending in the application.
- 4a) Of the above claim(s) 8-11, 44 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12-17, and 19-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's amendment of claims 1-4, 12-17, 19, 33, and 46-54; and the cancellation of claims 5, 6, 18, and 46-54 in the paper filed on 07/23/2009 is acknowledged. Claims 8-11, 44, and 45 remain withdrawn.

Claims 1-4, 12-17, and 19-43 are pending and at issue.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Priority**

2. Receipt of certified English translation of foreign application has already been acknowledged. Acknowledgment was made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f) in the Advisory Action mailed on 12/05/2008. Receipt has been acknowledged of the certified English translations of the 2003-378039 application filed in Japan and 2004-121080 application filed in Japan and submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file (see section 5 of Office Action mailed on 08/20/2008). Copies of the certified copies of the priority documents have been received.

**Rejections that are Withdrawn**

***Claim Rejections Withdrawn - 35 USC § 112 First Paragraph***

3. The rejections of claims 1-4 and 12-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. Applicant has amended the claims to recite a length of the oligonucleotide which overcomes this rejection.
4. The rejections of claims 23, 29, 35, and 41 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. Applicant has amended antecedent claim 1 to recite a length of the oligonucleotide which overcomes this rejection.
5. The rejections of claims 24, 30, 36, and 42, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. Applicant has amended antecedent claim 1 to recite a length of the oligonucleotide which overcomes this rejection.
6. The rejections of claims 25, 29, 37, and 43 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. Applicant has amended antecedent claim 1 to recite a length of the oligonucleotide which overcomes this rejection.
7. The rejections of claims 26, 32, and 38 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. Applicant has amended antecedent claim 1 to recite a length of the oligonucleotide which overcomes this rejection.

**Rejections that are Maintained**

***Claim Rejections Maintained - 35 USC § 103***

8. The rejection of claims 1-4, 23, 29, and 41 under 35 U.S.C. 103(a) as being unpatentable over Morita et al (Jan. 2002, cited on the IDS), Braasch et al. (2001), and Orum et al. (1999, noting this is reference no. 29 of Braasch et al.) is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that the claimed invention of a 2'-O, 4'-C-ethylene nucleotide (ENA) at the third position in an oligonucleotide from the 3' end would not have been obvious to one of ordinary skill in the art at the time of the claimed invention; due to the advantageous result obtained when the corresponding natural oligonucleotide primer is substituted in the third position from the 3' end substitution with an ENA, which ENA substituted oligonucleotide when used as a primer selectively amplifies the gene of interest (216 base pairs) as compared to the natural oligonucleotide used as a primer (see pages 27 and 28 of Remarks filed on 07/23/2009). However, Applicant has not provided any evidence that LNA substitution in the third position from the 3' end of the oligonucleotide would not have the same or similar property as the ENA substitution in the third position from the 3' end of the oligonucleotide, and has not provided any evidence rebutting the teaching that ENA substitution of LNA was known and obvious, prior to the claimed invention. LNA substitution in third position from the 3' end of an oligonucleotide is taught by Braasch et al. (see Table 3 of) and Orum et al. further teach oligonucleotides comprising LNA substitutions (entire publication, especially Table 1). The substitution of ENA for LNA is taught by Morita et al. (entire article, especially the

Abstract). Thus it would have been obvious to one of ordinary skill at the time of the claimed invention to substitute the ENA of Morita et al. for the LNA of Braasch et al. or Orum et al. to arrive at the claimed invention of an oligonucleotide having an ENA substitution in the third position from the 3' end. And thus Applicant's argument is not persuasive, as Applicant is arguing advantageous results of ENA substitution for natural nucleotides, when the rejection was made on the obviousness of ENA substitution for LNA nucleotides.

It is further noted that the preamble claim recitation of "for a primer" is an intended use and carries no patentable weight.

It is also noted that Braasch et al. teach an oligonucleotide of 18 bases in length and further that this oligonucleotide has a LNA substitution in the third position from the 3' end (see entry number 35 in Table 3). Thus Applicant's argument, that an oligonucleotide of 25 bases in length would not have been obvious, is not persuasive.

9. The rejection of claims 12-17 and 19 under 35 U.S.C. 103(a) as being unpatentable over Morita et al (Jan. 2002, cited on the IDS), Braasch et al. (2001), Orum et al. (1999, noting this is reference no. 29 of Braasch et al.), and Weston et al. (U.S. Patent No. 6,391,593 issued 2002, previously cited) is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that Weston et al. does not teach the claimed invention of a 2'-O, 4'-C-ethylene nucleotide (ENA) at the third position in an oligonucleotide from the 3' end. However, Weston et al. is not relied upon for this teaching, Morita et al., Braasch

et al., and Orum et al. in combination are relied upon for this teaching as given above. As the argued limitations are obvious in view of Morita et al., Braasch et al., and Orum et al. as given above, this rejection is also maintained.

10. The rejection of claims 20-22, 24-28, 30-40, and 42-43 under 35 U.S.C. 103(a) as being unpatentable over Morita et al., Braasch et al., and Orum et al. as applied to claims 1-4 above, and further in view of Stanton et al. (US publication No. 20010034023 published 2001 and previously cited) is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that Stanton et al. does not teach the claimed invention of a 2'-O, 4'-C-ethylen nucleotide (ENA) at the third position in an oligonucleotide from the 3' end. However, Stanton et al. is not relied upon for this teaching, Morita et al., Braasch et al., and Orum et al. in combination are relied upon for this teaching as given above. As the argued limitations are obvious in view of Morita et al., Braasch et al., and Orum et al. as given above, this rejection is also maintained.

**New Objections and Rejections Necessitated by Amendment**

***Claim Rejections - 35 USC § 112, Second Paragraph***

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-4 and 20-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 recite an oligonucleotide "for a primer" which is indefinite as it is unclear what this phrase means. Does it mean the oligonucleotide is a target for a primer? Does it mean the oligonucleotide is to be used as a primer? Or is some other meaning intended? Dependent claims 20-43 are thus also indefinite.

### **Conclusion**

13. No claim is free of the prior art.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples  
/M. S./  
Examiner, Art Unit 1637  
October 29, 2009

/Kenneth R Horlick/  
Primary Examiner, Art Unit 1637